

Section 5

510(k) Summary or 510(k) Statement

Premarket Notification [510(k)] Summary

OCT 29 2010

(Provided in conformance with 21 CFR 807.92)

1. Submitter:

Company Name and Address: Fulcrum Medical, Inc
17209 Chesterfield Airport Rd.
Chesterfield, MO 63005

Contact Person: Ryan S. Brame, Ph.D.
Contact Title: President
Contact Phone: 800-515-9132
Contact Fax: 888-788-5946

Date of Summary: May 28, 2010

2. Device Name and Classification:

Trade Name: fulAccess
Common and Usual Name: Medical Imaging Software
Classification Name: Image Processing System, Radiology
(21 CFR 892.2050)
Regulatory Class: Class II
Product Code: LLZ

3. Predicate Device(s):

K071964	MIM 4.1	MIMVista Corporation
K081076	Velocity AI.	Velocity Medical Solutions, LLC

4. Description of Device:

fulAccess is a standalone software product that provides basic image processing and communication functionality for use in radiology, oncology, and other clinical specialties. With fulAccess the user can review images from different modalities including CT, MR, and PET, perform basic functions including zoom, pan, measure, sample pixel intensity, and make annotations. Users may also create and save a set of files that include a copy of the data being viewed, any annotations, and an instance of the viewer executable. These files can be stored locally or on portable media (e.g. CD and DVD).

fulAccess is a Windows application and will be used on recommended hardware that is provided by the company or the end user.



5. Indication for Use:

fulAccess is a stand-alone software package that assists users in the display, analysis, comparison and communication of medical imaging data from various sources. It allows the display, analysis, annotation, and communication of medical images. The intended users of fulAccess are trained medical professionals including physicians, nurses, physicists and other medical technologists. fulAccess is not intended for use in mammography.

6. Comparison with Predicate Devices:

fulAccess is substantially equivalent to the identified predicate devices. The fulAccess product is similar in characteristics, materials, and features, and has similar technological features, intended use and indications for use as the predicates, and does not pose any new issues of safety and effectiveness.

A detailed comparison can be found in Section 12 of this submittal.

7. Non-Clinical Performance Summary

Fulcrum Medical has verified and validated that the fulAccess software meets its functional specifications and performance requirements. Verification testing was accomplished using a combination of unit, system and integration tests. Verification testing was organized with reference to discrete units of software functionality (e.g., DICOM import, image control, structure control, data export/saving, etc.) and the results of hazard analyses. All verification tests were passed and no anomalies remained at the conclusion of testing. Validation testing was performed by a board certified clinician who organized the testing according to the intended clinical use (i.e. importing data, viewing data, manipulating data, saving data, etc.). Validation testing was performed in a simulated clinical environment using a variety of data types and combinations that were judged by the clinician to be representative of the types of data the device will encounter in clinical use. All validation tests were passed and no anomalies remained at the conclusion of testing.

8. Conclusions

In summary, Fulcrum Medical, Inc. is of the opinion that fulAccess does not introduce any new potential safety risks, is as effective, and performs as well as devices currently on the market, and thus concludes that the fulAccess software is substantially equivalent to the predicate devices.



K101707
P. 2 of 2



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Scott Brame
President
Fulcrum Medical, Inc
17209 Chesterfield Airport Rd.
CHESTERFIELD MO 63005

OCT 29 2010

Re: K101707
Trade Name: fulAccess
Regulation Number: 21 CFR § 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: September 21, 2010
Received: October 1, 2010

Dear Mr. Brame:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Section 4

Indications for Use Statement

510(k) Number (if known) K101707

OCT 29 2010

Device Name: fulAccess

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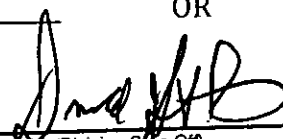
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X

OR

Over-The-Counter Use _____

(Per 21 CFR 801.109)


(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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K101707
P. 1 of 1

